

Message

From: Hart, Ellen [Ellen.Hart@fda.hhs.gov]
Sent: 11/10/2021 8:19:27 PM
To: Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]
Subject: RE: [EXTERNAL] RE: Seresto analysis technical discussion (EPA and FDA)

Thanks Colleen – 11 am would be preferable for me.
Ellen

From: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Sent: Wednesday, November 10, 2021 2:31 PM
To: Hart, Ellen <Ellen.Hart@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Seresto analysis technical discussion (EPA and FDA)

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Thanks Ellen! That sounds like a plan.

I was just chatting with Jackie and she said you would also be attending the smaller vet meetings. I heard back from Kelly and Coke this AM that Thursday 11/18 at 11 am or 1 pm works for them for our first meeting. Do either of those times also work for you?

I will likely send the invite Monday AM, as I am out from this afternoon until Monday morning.

Enjoy the holiday tomorrow as well!
Thanks -
Colleen

From: Hart, Ellen <Ellen.Hart@fda.hhs.gov>
Sent: Wednesday, November 10, 2021 12:59 PM
To: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Subject: RE: [EXTERNAL] RE: Seresto analysis technical discussion (EPA and FDA)

Thanks Colleen and sorry I was out on Monday – I checked with our team and this looks great! Thank you so much for capturing everything! Please let me know what else you need from us (or me). Hopefully once we get a handle on the plan for case review we can get closer to giving ourselves an expected timeline for all the moving pieces.

Thanks again and enjoy tomorrow's holiday!
Ellen

From: Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>
Sent: Tuesday, November 9, 2021 4:15 PM
To: Hart, Ellen <Ellen.Hart@fda.hhs.gov>; Miller, David <Miller.DavidJ@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Hugunin, Kelly <Kelly.Hugunin@fda.hhs.gov>; Clarke, Angela <Angela.Clarke@fda.hhs.gov>; Niman, Aaron <niman.aaron@epa.gov>; Britt, Adrian <Britt.Adrian@epa.gov>; Dunbar, Anwar <Dunbar.Anwar@epa.gov>; Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; Carey, Chieko (Coke) <Chieko.Carey@fda.hhs.gov>; Backus, Byron <Backus.Byron@epa.gov>; Jennings, Susan <Jennings.Susan@epa.gov>

Cc: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>

Subject: [EXTERNAL] RE: Seresto analysis technical discussion (EPA and FDA)

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Hi all –

Thanks for a good discussion yesterday!

Below are some notes I made embedded in the agenda items we had discussed. At the bottom of the email are the Action items I identified – please let me know if I missed anything or you have any questions.

Thanks!

Colleen

Agenda for 11/8 meeting:

Tentative timeline for coming weeks – Planning to initiate causality reviews next week, we will use summarized data currently available initially

Initiation of causality review

Anticipated vet staffing, schedule and meetings – Anticipate 2 EPA vets (Colleen, Julie) and 1 FDA vet (Coke) primarily for case reviews, Kelly (FDA) may assist some, will attend meetings

Data needed to prepare for review - We looked over some sections of the companion animal study reports (pre-registration material) and flumethrin HHRA; it seems like there may be enough there to start with for causality, but still need to look through data in context of case reviews to see what else might be helpful, particularly regarding PK analyses; HED toxicologists (RAB1 and RAB6) have prepared a proposal for how they will approach the studies that were submitted in the spreadsheet

Discuss available tox summaries – other formats needed/useful?

Other submissions from registrant (excel spreadsheet) – other studies relevant or review needed (for tox or PK data) – when needed?

Any other data?

Methodology for causality review –we will follow the FDA usual methodology (modified Kramer); will discuss more in the smaller meeting next week

Severe signs to also include – Discussed how we could extract a list of clinical signs seen most frequently in the adverse events/incidents; HED-CEB will provide the list they have available as well as the raw data used for stats to FDA, may need more discussion on this for what is most helpful to provide regarding the raw data

Template for format of assessment Briefly discussed the template that is available on the N drive that was provided by FDA; seems like will be useful model to follow when organizing the final report and/or have folks contribute to as we go

Format and timing of meetings going forward meeting time may be moved from Monday as not best time for everyone; also may be meeting more frequently with smaller group when doing causality review so may not need as many larger group meetings, will evaluate as we go; also, realized that next meeting for this group is week of Thanksgiving so may be impacted by leave etc., will query the group next week to see if needed

Action Items:

- Colleen to schedule first meeting with vets next week to initiate causality analysis
- Colleen/HED-CEB/FDA to work together to generate list of clinical signs to focus case review, provide raw data for stats analysis to FDA

- Colleen will look over the proposal prepared by HED RAB1/RAB6 re: study reviews and provide feedback, may coordinate with others on thoughts on when/how would incorporate studies
- HED RAB1/RAB6 to extract and provide the most useful summary sections of the imidacloprid/flumethrin HHRAs (appendices and DER summaries, I think were the main parts we identified; I might have the exact terms wrong)
- RD (?) to provide a list/table of the companion animal studies that were conducted for registration of collar (specific studies, species tested, # of animals, etc.)